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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,750	09/05/2003	Johnson E. Goode	P0011367.00	9063

27581 7590 04/21/2008

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EXAMINER	
MEHTA, BHISMA	

ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
04/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/656,750	GOODE ET AL.	
	Examiner	Art Unit	
	BHISMA MEHTA	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 March 2008* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because:
> Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Drawings

2. The drawings were received on March 14 2008. These drawings are not acceptable as Figure 3 as amended in not acceptable and the figures are not clear. Specifically, changes have been made to Figure 3 in the replacement sheet which alter what was shown originally in Figure 3. The addition of the braiding (149) is acceptable as this was in response to the objection that the outer layer having a stainless steel braiding along the first portion and being non-braided along the second portion was not shown in the originally filed Figure 3. However, the alterations such as the changed location of the anchoring band (160), the removal of the solid line adjacent the anchoring band, and the changed location and appearance of the compressible member are not acceptable. Furthermore, applicant is requested to submit an explanation, in detail, of all changes which are made to the originally filed drawings. This objection was previously given in the office action mailed on November 9 2006. In response to the office action of November 9 2006, Applicant filed drawings which were

received on September 17 2007 which overcame the objections but which were not clear as the features in the drawings received on March 9 2007. Applicant needs to submit a replacement sheet for Figure 3 with the changes as shown in Figure 3 of September 17 2007 but shown clearly such as in the drawings received on March 9 2007. Furthermore, replacement sheets should be submitted for all of the figures submitted on March 14 2008 as these figures are also not as clear as the drawings received on March 9 2007. Applicant's amendment of Figure 4 to include reference character 157 is acknowledged.

Specification

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to disclose the medical therapy delivery device having an anchoring device positioned along a distal end of the second portion and fixedly engaged with the manipulator wire.

Claim Objections

4. Claims 23-40 are objected to because of the following informalities: Claims 23 and 40 should have been submitted with the proper heading of "(Currently amended). With regards to these claims, the correct heading should be used. Appropriate correction is required.

5. Claims 13-15, 17, 21, and 23-40 are objected to because of the following informalities: Claim 13 recites the limitation "the anchoring band" in lines 2-3. Claim 21 recites the limitation "the anchoring band" in line 11. Claim 23 recites the limitation "the anchoring band" in line 25. Claim 40 recites the limitation "the anchoring band" in line 35. There is insufficient antecedent basis for this limitation in these claims. Appropriate correction is required.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1, 6-12, 16, 19, 20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wardle (U.S. Patent No. 4,748,969) in view of Truckai (U.S. Patent No. 5,397,304).

Wardle discloses a medical therapy delivery device having a shaft with a first portion (14) and a second portion (12). As shown in Figure 4, a deflectable tip (48) extends distally from the second portion and has a tapered portion and a tip lumen (shown at 58). The device also includes a manipulator wire (40) that extends through the shaft and a thru lumen tubing (32) having a thru lumen. In Figures 2 and 5, the outer layer of the shaft forms a single shaft lumen having a first lumen portion (shown at 28 in Figure 2 and at 6 in Figure 5) positioned about

the thru lumen tubing and a second lumen portion (shown above the portion shown at 28 in Figure 2 and above the portion shown at 6 in Figure 5) having a first side wall, a second side wall, and a bottom side wall which position the manipulator wire within the second lumen portion. The second lumen portion is offset from and in fluid communication with the first lumen portion. As to claim 11, as shown in Figure 4, an anchoring device or band (72) is positioned along a distal end of the second portion and is fixedly engaged with the manipulator wire (40). Also shown is the manipulator wire (40) that extends through the transition lumen of the transition tubing (30). As to claim 16, Wardle discloses a portion (50) of the thru lumen tubing is capable of sliding within the shaft during deflection of the second portion of the shaft (lines 40-63 of column 7). As to claim 19, in Figure 5, Wardle shows the first and second flanges as claimed. As to claim 20, Figures 2 and 5 shows the thru lumen tubing (32), the first side wall, the second side wall, and the bottom side wall positioning the transition tubing (30) within the second lumen portion. As to claim 22, the first lumen portion is generally semi-circular in shape and the second lumen portion is generally rectangular in shape.

Wardle discloses the invention substantially as claimed. Even though Wardle discloses the second portion (12) to be deflectable relative to the first portion (14) and the first portion to be flexible only sufficiently such that the first portion can follow the contours of the passages through which the device is being entered, Wardle does not disclose the first portion as being non-deflectable and the transition tubing being formed of a polyimide material having a durometer

reading of 86D. Wardle is also silent on the thru lumen being formed by a polyether block amide material having a durometer reading of 72D. In Figures 1 and 2, Truckai shows a steerable medical device having a first non-deflectable portion (10) and a second portion (16) which is deflectable relative to the first portion. The device also has a thru lumen formed by a PEBA material with a durometer in the range of 30D to 60D and a polyimide transition tubing (58) through which a manipulator wire extends. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the first portion of Wardle as a non-deflectable as taught by Truckai as both Wardle and Truckai disclose steerable devices and Truckai teaches that it is well known to provide steerable devices with a non-deflectable first portion to allow for the accurate manipulation of the deflectable second portion. It also would have been obvious to one having ordinary skill in the art at the time the invention was made to make the thru lumen of Wardle from a PEBA material as taught by Truckai as both Wardle and Truckai disclose steerable devices having a thru lumen and Truckai teaches that it is well known to use PEBA for the material of the thru lumen. As to the limitation of the thru lumen tubing being formed polyether block amide having a durometer reading of 72D in claim 7, Truckai does disclose polyether block amide as a suitable material for a medical device and the parameter of the durometer reading of the thru lumen tubing is deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. It also would have been obvious to one having ordinary skill in the art at the time the invention was made

to make the transition tubing of Wardle from a polyimide material as taught by Truckai as both Wardle and Truckai disclose steerable devices having a transition tubing through which a manipulator wire extends and Truckai teaches that it would be advantageous to make the transition tubing from polyimide to provide lateral and torsional stiffness to the deflectable tip. As to the limitation of the polyimide material having a durometer reading of 86D, the parameter of the durometer reading is deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

As to claims 6, and 8-10, Wardle discloses the invention substantially as claimed. Wardle discloses that the tip includes a distal opening and, in Figure 4, the distance between the outer wall and inner wall gradually decreases between the proximal end and the distal end of the tapered portion. However, Wardle does not disclose the thicknesses of the walls of the deflectable tip or the diameters of the various components of the medical device. However, these parameters are deemed matters of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation, in determining optimum results.

8. Claims 2, 3, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wardle and Truckai as applied to claims 1 and 11 above, and further in view of Hayzelden (U.S. Patent Application Publication No. 2003/0050598).

Wardle and Truckai disclose the invention substantially as claimed. Even though Wardle teaches in line 61 of column 5 to line 14 of column 6 that the outer layer (66) is formed of a polymer and contain a stainless steel braiding (67) to provide torsional stiffness to the shaft, Wardle is silent on the outer layer being specifically formed of polyether block amide and including a stainless steel braiding and having a durometer reading of 72D along the first portion and being non-braided and having a durometer reading of 40D along the second portion. In Figures 1-3, Hayzelden shows the outer layer (42) of a medical device having a first portion (12) made of a high durometer (such as 63D) polyether block amide with a stainless steel braiding (44) and a second non-braided portion (14) and teach that the braiding provides reinforcement to the first portion. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the outer layer of Wardle with a polyether block amide as taught by Hayzelden as both Wardle and Hayzelden teach that it is well known to use polymer materials for medical devices and Hayzelden teaches the use of polymer materials such as polyether block amide. It would also have been obvious to one having ordinary skill in the art at the time the invention was made to make the first portion of the outer layer of Wardle with a high durometer (such as 63D) polyether block amide with a stainless steel braiding as taught by Hayzelden as both Wardle and Hayzelden disclose devices having a deflectable second portion and Hayzelden teaches that it would be advantageous to reinforce the first portion to allow for the proper deflection of the second portion when it is being used in a surgical procedure. As to the limitation of the first portion having a

durometer reading of 72D and the second portion having a durometer reading of 40D, in lines 31-63 of column 16, Hayzelden teaches that the first portion (12) would have a higher durometer reading than the second portion (14) and that the second portion (14) is made to be sufficiently resilient or flexible and that material modifications can be made to suit the particular needs of the user. Therefore, the parameter of the durometer readings of the first portion and the second portion is deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. As to the limitation of the transition tubing having a length of approximately one inch in claim 18, the parameters of length is deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

9. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wardle and Truckai as applied to claim 1 above, and further in view of Hobbs et al (U.S. Patent No. 5,584,821).

Wardle and Truckai disclose the invention substantially as claimed. However, Wardle is silent on the deflectable tip being formed of a radio opaque and echo-genic polymer material. Hobbs et al disclose a medical device having a deflectable tip (16) made of a polyether block amide material loaded with tungsten. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the deflectable tip of Wardle from a radio opaque and echo-genic polymer material such as a polyether block amide material loaded with tungsten as taught by Hobbs et al as both Wardle and

Hobbs et al teach advancing a medical device in narrow vessels or cavities and Hobbs et al teach that it is beneficial to have a tip that allow the distal end of the medical device to be seen by the user as it is advanced in the body.

10. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wardle, Truckai, and Hobbs et al as applied to claim 4 above, and further in view of Kousai et al (U.S. Patent No. 4,778,455).

Wardle, Truckai, and Hobbs et al disclose the invention substantially as claimed. Even though Hobbs et al disclose a medical device having a deflectable tip (16) made of a polyether block amide material loaded with tungsten, Hobbs et al are silent on the deflectable tip being formed of a radio opaque and echo-genic polymer material such as tungsten carbide and having a durometer of 35D. Kousai et al disclose a medical device having a tip (1) made of a polymer material loaded with tungsten carbide. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the tungsten of Hobbs et al with tungsten carbide as taught by Kousai et al as both Hobbs et al and Kousai et al teach advancing a medical device in narrow vessels or cavities and Kousai et al teach that it is well known to use tungsten or tungsten carbide in the distal tip to allow the distal end of the medical device to be seen by the user as it is advanced in the body. As to the limitation of the PEBA material having a durometer reading of 35D, the parameter of the durometer reading is deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

11. Claims 13-15, 17, 21, 23-26, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wardle and Truckai as applied to claims 11and 1 above, and further in view of Ponzi (U.S. Patent No. 5,897,529).

Wardle and Truckai disclose the invention substantially as claimed as discussed above. Even though Wardle discloses the medical device having a compressible member through which the manipulator wire extends and the distal end of the compressible member fixedly engaged with the outer layer (lines 15-40, column 6), Wardle is silent on the specifics of the compressible member being positioned between the distal end of the transition tubing and the anchoring band and being free to move relative to the manipulator wire and the shaft during deflection of the second portion. In Figure 2, Ponzi shows a steerable medical device having a compressible member (44) through which a manipulator wire (42) extends. In lines 14-45 of column 6, Ponzi teaches that the compressible member is anchored at its proximal end and distal end thus allowing it to move freely relative to the manipulator wire and the shaft during defection. The wire preferably has a diameter ranging from about 0.006 to 0.010 inches. The inner diameter of the compressible member is preferably slightly larger than the diameter of the manipulator wire. It would have been obvious to one having ordinary skill in the art at the time the invention was made to position the compressible member of Wardle between the distal end of the transition tubing and the anchoring band where the distal end of the compressible member is fixedly engaged with the outer layer so that the compressible member can move freely as taught by Ponzi as both Wardle and Ponzi disclose steerable devices

having a compressible member through which a manipulator wire extends and Ponzi teaches that it would be advantageous to have a compressible member to provide flexibility to the deflectable portion of the steerable device. As the limitation of the diameters of the compressible members in claim 14, the parameter of diameters is deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. As to the limitation of the transition tubing having a stiffness greater than the compressible member in claim 17, it would be obvious to one having ordinary skill in the art at the time the invention was made that transition tubing of Wardle would be stiffer than the flexible compressible member of Ponzi as the compressible member is in the second deflectable portion of the shaft. As to claim 25, Wardle, Truckai and Ponzi do not disclose the specifically claimed diameters of the various components of the medical device. However, these parameters are deemed matters of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation, in determining optimum results. As to claim 40, the deflectable tip (48) is considered to be passively deflectable relative to the second portion and the thru lumen tubing (32) has an outer wall as shown in Figure 4. The outer layer of the shaft along the first portion (12) is of uniform thickness and has an inner wall which forms the single shaft lumen positioned about the thru lumen tubing (32) and the manipulator wire (40) where the manipulator wire is advanceable and retractable between an inner wall of the outer layer and an outer wall of the thru lumen tubing. Figures 2 and 5 shows the outer layer along the second portion of the

shaft where the outer layer forms the first lumen portion and the second lumen portion. The transition tubing (30) is positioned within the second lumen portion and extends between a proximal end of the second portion to a point along the second portion of the shaft as shown in Figure 3.

12. Claims 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wardle, Truckai, and Ponzi as applied to claim 26 above, and further in view of Hayzelden (U.S. Patent Application Publication No. 2003/0050598).

Wardle, Truckai, and Ponzi disclose the invention substantially as claimed. Even though Wardle teaches in line 61 of column 5 to line 14 of column 6 that the outer layer (66) is formed of a polymer and contain a stainless steel braiding (67) to provide torsional stiffness to the shaft, Wardle is silent on the outer layer being specifically formed of polyether block amide and including a stainless steel braiding and having a durometer reading of 72D along the first portion and being non-braided and having a durometer reading of 40D along the second portion. In Figures 1-3, Hayzelden shows the outer layer (42) of a medical device having a first portion (12) made of a high durometer (such as 63D) polyether block amide with a stainless steel braiding (44) and a second non-braided portion (14) and teach that the braiding provides reinforcement to the first portion. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the outer layer of Wardle with a polyether block amide as taught by Hayzelden as both Wardle and Hayzelden teach that it is well known to use polymer materials for medical devices and Hayzelden teaches the use of polymer materials such as polyether block amide. It would also have been obvious to one

having ordinary skill in the art at the time the invention was made to make the first portion of the outer layer of Wardle with a high durometer (such as 63D) polyether block amide with a stainless steel braiding as taught by Hayzelden as both Wardle and Hayzelden disclose devices having a deflectable second portion and Hayzelden teaches that it would be advantageous to reinforce the first portion to allow for the proper deflection of the second portion when it is being used in a surgical procedure. As to the limitation of the first portion having a durometer reading of 72D and the second portion having a durometer reading of 40D, in lines 31-63 of column 16, Hayzelden teaches that the first portion (12) would have a higher durometer reading than the second portion (14) and that the second portion (14) is made to be sufficiently resilient or flexible and that material modifications can be made to suit the particular needs of the user. Therefore, the parameter of the durometer readings of the first portion and the second portion is deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

13. Claims 28-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wardle, Truckai, Ponzi, and Hayzelden as applied to claim 27 above, and further in view of Kousai et al (U.S. Patent No. 4,778,455).

Wardle, Truckai, Ponzi, and Hayzelden disclose the invention substantially as claimed. Even though Hayzelden discloses a medical device made of a polymer such as PEBA, Wardle, Truckai, Ponzi, and Hayzelden are silent on the deflectable tip being formed of a radio opaque and echo-genic polymer material such as tungsten carbide and having a durometer of 35D. Kousai et al disclose a

medical device having a tip (1) made of a polymer material loaded with tungsten carbide. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the deflectable tip of Wardle with tungsten carbide as taught by Kousai et al as Kousai et al teach that it is well known to use tungsten carbide in the distal tip to allow the distal end of the medical device to be seen by the user as it is advanced in the body. As to the limitation of the PEBA material having a durometer reading of 35D, the parameter of the durometer reading is deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. As to the limitation of the polyimide material having a durometer reading of 86D, the parameter of the durometer reading is deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. As to the limitation of the diameters of the compressible members in claim 35, to the limitation of the diameters of the various components of the medical device in claims 36 and 37, and to the limitation of the transition tubing having a length of approximately one inch in claim 39, the parameters of diameter and length are deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

Response to Arguments

14. Applicant's arguments with respect to claims 1-40 have been considered but are moot in view of the new ground(s) of rejection. As to Applicant's remarks

in line 23 of page 14 to line 7 of page 15 of the amendment received March 14 2008, Wardle does disclose a deflectable tip as shown in Figure 2 where the deflectable tip (48) is the portion that extends distally from the second portion (12). The deflectable tip has a tapered portion which is the section of the tip at the opening and which is located between the proximal end of the tip and the distal tip. As to Applicant's remarks in lines 14-25 of page 16, Wardle does teach a compressible member (64) positioned between the distal end of the transition tubing and the anchoring band (72) where the manipulator wire (40) extends through the compressible member (Figure 2, lines 1-23 of column 5, and line 64 of column 7 to line 12 of column 8).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through

Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bhisma Mehta/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767